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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,801	11/30/2001	Valerie Bush	P-5437	2661

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Alan W. Fiedler
Becton Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417-1880

EXAMINER
SUN, XIUQIN

ART UNIT	PAPER NUMBER
2863	

DATE MAILED: 05/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/996,801	Applicant(s) BUSH ET AL.	
	Examiner Xiuqin Sun	Art Unit 2863	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18,20-24 and 26-30* is/are rejected.

7)☒ Claim(s) *19 and 25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed on 06/19/2002 has been received; however, the references have not been considered by the examiner because they do not contain sufficient information, Specifically, the references short of a date which is required by MPEP 609.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-18, 20-24 and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parris et al. (U.S. Pub. No. 20020026110 A1) in view of Wittwer et al. (U.S. Pat. No. 6303305 B1) and Samsoondar (U.S. Pub. No. 20030078746 A1).

Parris et al. teach a method of predicting a value of an analyte in a sample at a known time (section 0007, lines 1-7 and section 0008, lines 1-14), said method comprising the steps of: making a plurality of observations on a plurality of samples, wherein each observation includes a plurality of variables associated with said samples (sections 0011-0013, 0038, 0067 and section 0110, lines 1-5);

generating an equation which approximates said plurality of observations (sections 0011-0017, 0033, 0034, 0107, 0110-0115, 0118-0131); measuring a sample analyte value (sections 0038, 0132 and 0133), said sample having associated therewith a storage time, and a storage temperature (sections 0066, 0072, 0080, 0140, 0179, 0197-0199); inputting said storage time and said storage temperature into said equation, and obtaining an estimated analyte value, wherein the difference between said estimated analyte value and said measured analyte value can be used to calibrate said equation (sections 0007, 0008, 0016, 0017, and 0133-.0135). Parris et al. further teach the method steps of: determining a level of an analyte in a sample, said sample having associated therewith at least one factor selected from the group consisting of a container type, a storage time, and a storage temperature (sections 0038, 0066, 0072, 0080, 0132, 0133, 0140, 0179, and 0197-0199); inputting said at least one factor and said analyte level into an equation, and solving said equation to obtain an estimated initial analyte value (sections 0007, 0008, 0016, 0017, and 0133-0135). Parris et al. further teach a system for estimating a value of analyte in a sample, said system comprising: an analyzer adapted to analyze the actual level of an analyte in a sample, an estimator adapted to estimate said level of said analyte based on a plurality of values, said values including said actual level of said analyte, a storage time, and a storage temperature, and an output adapted to present said estimated value (sections 0135, 0066, 0067, 0072, 0080, 0140, 0179, and 0197-0199). Parris et al. further teach a method of generating a predictive model for predicting a value of an analyte in a sample, the method

comprising the steps of: collecting a plurality of samples (sections 0011 and 0067); testing each sample for an initial value of an analyte (sections 0110-0115, 0118-0132); storing at least one sample at a known storage temperature (sections 0110, -0115, 0118-0132 and 0197-0199); testing each sample for a subsequent value of said analyte after a known time interval (sections 0110, -0115, 0118-0132); analyzing data based on said tests using polynomial regression analysis (sections 0110, -0115, 0118-0132); and generating a predictive model based on said analysis (sections 0110, -0115, 0118-0132). Parris et al. further teach a computer-readable medium of instructions, adapted to control the said system to implement the said method for generating a predicted analyte value discussed above (sections 0065, 0070, and 0135). Parris et al. further teach: solving said equation for an analyte value as a function of storage time and storage temperature (sections 0007, 0008, 0016, 0017, 0066, 0067, 0072, 0080, 0133-0135, 0140, 0179, and 0197-0199); said sample is a blood sample (section 0067); said plurality of variables associated with said sample comprises an actual initial analyte level, an actual subsequent analyte level, a time since the sample was taken, and a temperature at which said sample was stored (sections 0110-0115, 0118-0132 and 0197-0199); said equation represents analyte level as a function of storage time (sections 0011-0017, 0033, 0034, 0107, 0110-0115, 0118-0131); said equation represents analyte level as a function of storage temperature (sections 0197-0199); said equation represents analyte level as a function of storage temperature and storage time (sections 0011-0017, 0033, 0034, 0107, 0110-0115, 0118-0131 and

0197-0199); said estimator estimates said level of analyte using an equation associated with said analyte, said equation adapted to solve for an estimated analyte level as a function of actual analyte level, storage time, and storage temperature (sections 0135, 0066, 0067, 0072, 0080, 0140, 0179, and 0197-0199); validating the predictive model by comparing the true values to a set of model predicted values (sections 0007, 0008, 0016, 0017, and 0133- 0135); said step of validating further includes: accepting the model of the set of model predicted values that is more accurate than the set of subsequent values (sections 0007, 0008, 0016, 0017, and 0133- 0135); said computer-readable medium of instructions further adapted to generate said predictive model, and further comprising: a set of instructions, adapted to control said system to collect a plurality of data associated with a known set of samples, said known samples each having data associated therewith comprising an actual initial analyte value, an actual subsequent analyte value, and at least one factor from the group consisting of a time of storage, a temperature of storage (sections 0065-0067, 0070, 0135, 0072, 0080, 0140, 0179, and 0197-0199); said computer-readable medium of instructions further adapted to control said system to generate said predictive model from said data associated with said known set of samples (sections 0011, 0065-0067, 0070, 0135, 0072, 0080, 0140, and 0179); said computer-readable medium of instructions further adapted to control said system to validate the predictive model by comparing the true initial values to a set of model predicted values (sections 0133-135, 0065-0067, 0070, 0072, 0080, 0140, and 0179); said computer-readable medium of instructions further adapted to

control said system so accept the model if the set of model predicted values is more accurate than the set of subsequent values (sections 0133-135, 0065-0067, 0070, 0072, 0080, 0140, and 0179).

Parris et al. do not teach: measuring a sample analyte value, said sample having associated therewith a container type; inputting said container type, together with said storage time, said storage temperature, and said measured analyte value into said equation; and solving said equation to obtain an estimated initial analyte value.

Wittwer et al. disclose a method for quantification of an analyte, and teach the steps and means of: measuring a sample analyte value as a function of storage time; inputting said measured analyte value into a mathematical equation; and solving said equation to obtain an estimated initial analyte value (col. 3, lines 30-51; col. 4, lines 19-26 and lines 30-37).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the teaching of Wittwer et al. into the Parris system and adapt the Parris equation (for example, rewrite the Eqn. 1 into: $S_0 = S_\infty + (S_t - S_\infty)\, e^{kt}$) to derive an estimated initial analyte value from a measured instant analyte value (Wittwer et al., see Abstract and col. 3, lines 30-51).

Samsoondar suggests including the contribution of container type in a method for determining the concentration of an analyte in a sample (sections 0174, 0222 and 0375).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the teaching of Samsoondar in the Parris system in order to consider the variability contributed by container type in estimating an analyte value in a sample (Samsoondar, section 02221).

Allowable Subject Matter

4. Claims 19 and 25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Reasons for Allowance

5. The following is an examiner's statement of reasons for allowance:

The primary reason for the allowance of claim 19 is the inclusion of the limitation that said equation contains a quadratic term for time, a quadratic term for temperature, and a mixed term for time and temperature. It is this limitation found in the claim, as they are claimed in the combination, that has not been found, taught or suggested by the prior art of record which makes this claim allowable over the prior art.

The primary reason for the allowance of claim 25 is the inclusion of the method step of storing said samples at a plurality of known temperatures. It is this limitation found in the claim, as they are claimed in the combination, that has not been found, taught or suggested by the prior art of record which makes this claim allowable over the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Contact Information

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiuqin Sun whose telephone number is (703)305-3467. The examiner can normally be reached on 7:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Barlow can be reached on (703)308-3126. The fax phone numbers for the organization where this application or proceeding is assigned are (703)872-9318 for regular communications and (703)872-9319 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0956.

XS

XS
May 11, 2003

John Barlow
Supervisory Patent Examiner
Technology Center 2800